Media Fact Sheet: Canagliflozin Phase 3 Program

Understanding the Phase 3 Program

FAST FACTS

- **The global Phase 3 program evaluated the safety and efficacy of investigational antihyperglycemic agent canagliflozin, a selective sodium glucose co-transporter 2 (SGLT2) inhibitor, and enrolled 10,285 patients in nine studies.**
- **The trials assessed the safety and efficacy of canagliflozin dosed at 100 or 300 mg once daily, when used as monotherapy and in combination with oral antihyperglycemic agents, and in combination with insulin with or without oral antihyperglycemic agents.**

- All clinical trials were global, randomized and double-blind, and were either placebo- or active comparator-controlled.

- The Phase 3 clinical program evaluated the safety and efficacy of investigational canagliflozin across the spectrum of type 2 diabetes management, from adult patients treated only with diet and exercise to those requiring insulin injections to maintain glycemic control, and in three large studies in special populations: older patients with type 2 diabetes, patients with type 2 diabetes who had moderate renal impairment, and patients with type 2 diabetes who had or were at high risk for cardiovascular disease.

- CANTATA (**CAN**agliflozin **T**reatment **A**nd **T**rial **A**nalysis) includes multiple studies assessing the glucose-lowering efficacy and safety of canagliflozin in adult patients diagnosed with type 2 diabetes failing to achieve glycemic control on diet and exercise and on the background of a variety of commonly used oral antihyperglycemic agents or insulin.

- CANVAS (**CAN**agliflozin cardio**V**ascular **A**ssessment **S**tudy) assesses the general safety, tolerability and cardiovascular safety of canagliflozin in approximately 4,330 adult patients with type 2 diabetes, who also have either a history or high risk of cardiovascular disease.

Phase 3 Clinical Development Program: 9 Studies Conducted